

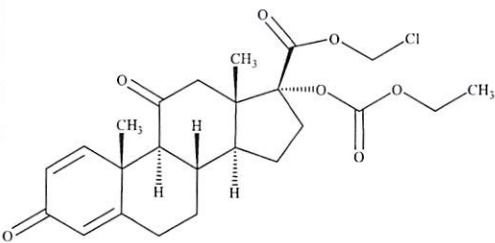
## Certificate of Analysis

Certificate No.: 20250321019



Date: March 21, 2025

Retest date: March 20, 2028

<b>Compound Name:</b> Loteprednol Impurity 8	
<b>Synonyms:</b>	chloromethyl (8S,9S,10R,13S,14S,17R)-17-((ethoxycarbonyloxy)-10,13-dimethyl-3,11-dioxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthrene-17-carboxylate
<b>TLC Catalogue Number:</b>	L-3912
<b>CAS Number:</b>	207670-54-0
<b>Alternate CAS Number:</b>	N/A
<b>Molecular Weight:</b>	464.94
<b>Molecular Formula:</b>	C <sub>24</sub> H <sub>29</sub> ClO <sub>7</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	2423-002A4
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO



Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.7%</b>
<b>Impurity (HPLC)</b>	RT 9.30, 0.17%	
<b>Water Content (KF)</b>	N/A	<b>0.1%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{20.0}$ (c=1.11, CHCl <sub>3</sub> ): <b>+107.4°</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (%)</b>	Not less than 90.0%	<b>99.6%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/21/2025
Approved by:	Quality Assurance		03/21/2025

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.